# EXHIBIT 11

# Section 1498(A) is Not a Rx to Reduce Drug Prices

SUSAN G. BRADEN & JOSHUA A. KRESH*

## ABSTRACT

On June 20, 2018, *The New York Times* published an editorial captioned "How the Government Can Lower Drug Prices," announcing that "a possible solution involves an obscure part of federal law known as Section 1498. The provision acts as a sort of eminent domain for patented inventions allowing the government to circumvent patent protections if the patent holder is compensated. In the case of a pharmaceutical, the Department of Health and Human Services (HHS) can authorize a drug maker to produce a low-cost generic version, which it would then buy in bulk."[1] The authority cited by *The New York Times* for this proposition was a 2016 law review article published in the *Yale Journal of Law & Technology* (Yale Article).[2]

Fast forward to March 23, 2021. Within weeks of President Biden's inauguration, Senator Bernie Sanders delivered the Opening Statement at a Senate Committee on Health, Education, Labor, and Pensions Subcommittee hearing citing *The New York Times* editorial as support for the introduction of S. 909, the Prescription Drug Price Relief Act of 2021, proposed legislation that would authorize the HHS Secretary to infringe on pharmaceutical patents or require pharmaceutical patent owners to enter compulsory licenses at royalty rates established by HHS should those patent owners be found to have charged excessive rates for the drug in question.[3]

On February 17, 2022, Senators Elizabeth Warren and Angus S. King, Jr., with Congressman Lloyd Doggett, wrote a letter to HHS Secretary Xavier Becerra urging

* Judge Susan G. Braden (Ret.) served as Chief Judge and Judge, United States Court of Federal Claims (2003–2019). She is a Jurist-In-Residence, Center for Intellectual Property X Innovation Policy, Antonin Scalia Law School George Mason University; United States Patent & Trademark Office (USPTO) Private Patent Advisory Committee (PPAC); Public Member, Administrative Conference of the United States; Legal Policy Advisory Board, Washington Legal Foundation; Board of Directors, United Inventors Association; and Board of Advisors, New Civil Liberty Alliance. The views expressed herein do not represent those of the USPTO nor the PPAC nor any other organization with which she is affiliated; they are the views of the author. Joshua A. Kresh is Managing Director of Center for Intellectual Property X Innovation Policy, Antonin Scalia Law School, George Mason University. Our colleague, Professor Sean M. O'Connor, provided the idea, inspiration, and support for this Article. The authors also express our appreciation for the insightful comments of academic, practitioner, and policymakers who support the rights of patent owners.

[1] *How the Government Can Lower Drug Prices*, N.Y. TIMES: EDITORIALS (June 20, 2018), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html.

[2] Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016).

[3] Prescription Drug Price Relief Act of 2021, S. 909, 117th Cong. (2021); *Why Does the U.S. Pay the Highest Prices in the World for Prescription Drugs*, *Hearing Before the Subcomm. on Primary Health and Ret. Sec.*, 116th Cong. (Mar. 23, 2020), https://www.help.senate.gov/hearings/why-does-the-us-pay-the-highest-prices-in-the-world-for-prescription-drugs (opening statement of Senator Bernie Sanders).

him to use "existing executive authority" to lower drug prices.[4] On March 24, 2022, eight public interest groups forwarded the HHS Secretary a "Petition To Make Drugs More Affordable," citing the Yale Article.[5] On April 22, 2022, Senator Warren again wrote to the HHS Secretary attaching an April 22, 2022 letter from "over 25 legal and public health experts" describing 28 U.S.C. § 1498 as the "government patent use power," i.e., a "tool" that can be used "to intervene when patients and public health are harmed by excessive drug prices."[6] The chief author of this letter is none other than one of the authors who penned the 2016 Yale Article. And, on June 23, 2022, eight Senators and 103 members of Congress sent a letter to the HHS Secretary to "utilize . . . government use compulsory licensing under 28 U.S.C. 1498 . . . to lower prescription drug prices."[7] In light of the close margins in the 118th Congress, continued pressure on the executive branch to exert 28 U.S.C. § 1498 (a) should be expected.

In *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928), however, the United States Supreme Court held that the "intention and purpose of Congress in the act of 1918 [(the predecessor to Section 1498)] was to stimulate contractors to furnish what was needed for [World War I], without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." In 1949, Congress amended the Act of 1918 to precisely limit Section 1498(a) solely as a waiver of sovereign immunity to provide a private party with standing and a judicial forum in which to sue the government for patent infringement.[8] No federal court, however, has held that the government has an absolute *right* to infringe privately held patent rights and therefore, historically, they have narrowly and strictly construed Section 1498(a), as we discuss below.

## I. INTRODUCTION

This Article argues that the authors of the Yale Article have misled some legislators and members of the public to believe government infringement of pharmaceutical

---

[4] Letter from Senator Elizabeth Warren, Senator Angus S. King, Jr., and Congressman Lloyd Doggett to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Feb. 17, 2022), https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf.

[5] Letter from Action Center on Race & the Economy, Center for Popular Democracy Action, Indivisible, People's Action, PrEP4All, Public Citizen, Social Security Works, and T1International, to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. 3 n. 9 (Mar. 24, 2022), https://www.citizen.org/article/make-meds-affordable-petition/ (introducing and including petition).

[6] Letter from Senator Elizabeth Warren to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.22%20Letter%20to%20Becerra%20on%20Drug%20Pricing%20Executive%20Authorities.pdf; Letter from Amy Kapczynski, JD, Aaron S. Kesselheim, MD, JD, MPH, Christopher J. Morten, JD, PhD, David Herman, Christopher Umanzor, to Senator Elizabeth Warren (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

[7] Letter from Elizabeth Warren et al. to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (June 23, 2022), https://www.warren.senate.gov/imo/media/doc/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices%20FINAL1.pdf.

[8] 28 U.S.C. § 1498(a); *see* Brennan et al., *supra* note 2, at 301 n.128; *see generally* Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145 (2012).

patent rights is sanctioned by Section 1498(a) and will reduce drug prices. First, we take issue with the Yale Article for its failure to cite empirical evidence that government infringement of pharmaceutical patents will lower drug prices. Next, we critique the Yale Article's proposal that HHS engage in the unprecedented misuse of executive authority to infringe on pharmaceutical patents, ignoring the history and limited scope of Section 1498(a), as reflected in decades of case law. Consequently, we believe that any unilateral executive action authorizing infringement of pharmaceutical patents or compelling owners of pharmaceutical patents to license them at royalty rates set by HHS, or another federal agency, should be nullified by the federal courts. If not, Section 1498(a) will require the government to pay pharmaceutical patent owners "reasonable and entire compensation" as damages, including lost profits. And those damages will be paid from congressional appropriations. As such, the misuse of Section 1498(a) is not a Rx for reducing drug prices, but in effect is a tax imposed on American citizens.

## II. NO EMPIRICAL EVIDENCE SHOWS THAT GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS WILL REDUCE DRUG PRICES

The Yale Article states with alarm that the cost of pharmaceuticals in the United States is "soaring," but admits the "increase in prescription spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HVC)."[9] The drug at issue was HARVONI™, a breakthrough patented pharmaceutical developed and manufactured by Gilead Sciences, Inc. (Gilead). The Yale Article asserts, based on inferences and assumptions, that "Gilead's prices vastly exceed the cost of producing these drugs."[10] The Yale Article accurately reports the initial list price of HARVONI™ was approximately $100,000 for a twelve-week regimen.[11] This initial price, however, was reduced by 46% within twelve months; by 2018, Gilead released its own generic drug, EPCLUSA™.[12] The myopic focus on the introductory price of these drugs, hyped by the Yale Article as an example of "one of the most pressing domestic policy issues in the United States today,"[13] however, did not take into account that new competition on the horizon could have a significant downward effect on these drug prices—which happened.

In 2017, the U.S. Food and Drug Administration (FDA) approved AbbVie, Inc.'s MAVYRET™, which reduced HCV treatment time to eight weeks at an estimated wholesale cost of $26,400.[14] A few months later, MAVYRET™ weekly new

---

[9] Brennan et al., *supra* note 2, at 277.

[10] *Id.* at 278.

[11] *Id.* at 277.

[12] Richard Staines, *Gilead Launches Generics of Own Hepatitis C Drugs in US to Cut Health Costs*, PHARMAPHORUM (Sept. 25, 2018), https://pharmaphorum.com/news/gilead-launches-generics-of-own-hepatitis-c-drugs-in-us-to-cut-health-costs/.

[13] Brennan et al., *supra* note 2, at 277.

[14] Ned Pagliarulo, *AbbVie Surprised Investors with its Hepatitis C Success. Will it Last?* BIOPHARMADIVE (Aug. 2, 2018), https://www.biopharmadive.com/news/abbvies-surprised-investors-mavyret-hepatitis-c-success-will-it-last/529158/; *see also* Press Release, AbbVie, AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1-6) in as Short as 8 Weeks, https://news.abbvie.com/news/abbvie-receives-us-fda-

prescriptions "outpaced" Gilead's HARVONI™ and EPCLUSA™.[15] As a result of these drugs, Hepatitis C virus-caused disease has steadily declined, leaving a "smaller and smaller pool of patients."[16] While the Yale Article was published in 2016 and subsequently did not have the benefit of this information, we are skeptical of the authors' contention that the price of HVC drugs raises "the problem that economists have long identified with patent-based drug pricing: the potential for massive social 'deadweight' losses that stem from supra-marginal cost pricing"[17] that must be remedied by the government's infringement of these patented pharmaceuticals. The *raison d'être* advanced for the federal government "breaking" pharmaceutical companies' patent rights is the promise of "significant social gains to be had from bringing compensation in line with the risk-adjusted cost of developing a drug."[18] Of course, these "social gains" are not identified, nor how the government will determine the "risk-adjusted cost of drug development," nor who within the government will decide when these "significant social gains" require infringing a patent issued by the United States Patent and Trademark Office (USPTO), the sole federal agency authorized by Congress "[t]o promote the Progress of Science . . . by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[19]

The Yale article also did not account for the subsequent development that both list and net prices of pharmaceuticals, primarily those composed of small-molecule drugs, began to fall around the time of its publication; a trend that has continued.[20] Biologics have become "the driver behind overall drug spending in the United States in recent years.[21] In inflation-adjusted terms, biologic drug spending increased from $291 to $435 per capita from 2014 to 2018, while small-molecule drug spending fell from $689 to $610 per capita during this same period."[22]

The following chart, based on data obtained and compiled by Drug Channels Institute, an organization that collects and reports on approximately 1,000 brand-name

---

approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.

15 Pagliarulo, *supra* note 14.

16 *Id.*

17 Brennan et al., *supra* note 2, at 279.

18 *Id.* at 282.

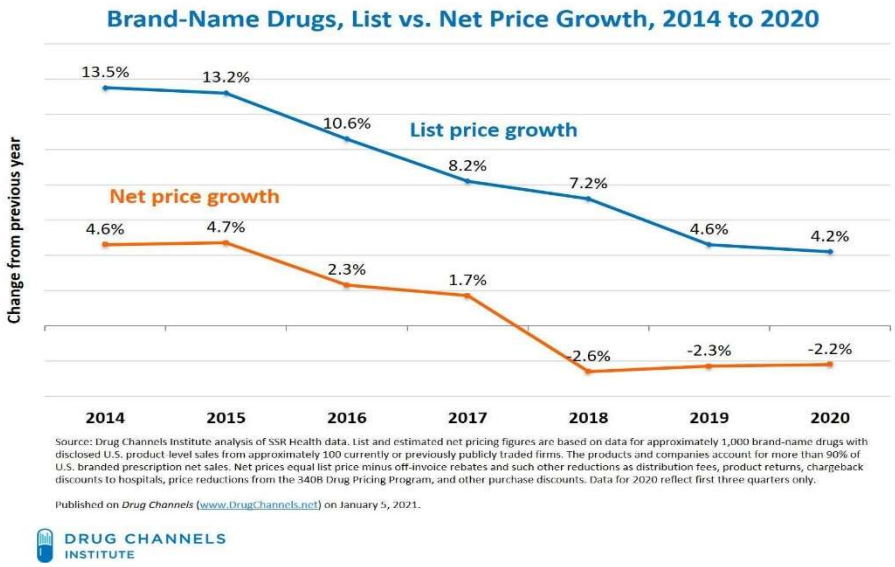
19 U.S. CONST. art. I., § 8, cl. 8.

20 A "small-molecule drug" is composed of "organic compounds affecting molecular pathways by targeting important proteins. These compounds have a low molecular weight, making them penetrate cells easily." Qingxin Li & CongBao Kang, *Mechanics of Action for Small Molecules Revealed by Structural Biology in Drug Discovery*, 21 INT'L. J. MOLECULAR SCI. 5262 (2020).

21 *What Are "Biologics" Questions and Answers*, U.S. Food and Drug Admin. (Feb. 6, 2018), https://www.fda.gov./about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (defining a "biologic drug" as being composed of "sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues." Biologic drugs are not easily identified or characterized and are extremely sensitive to environmental factors such as heat and microbiological contamination); *see also Why Does the US Pay the Highest Prices in the World for Prescription Drugs*? *Hearing Before the Subcomm. on Primary Health and Retir. Sec.*, 117th Cong. 2 (Mar. 23, 2021) (statement of Alex Brill, Resident Fellow, American Enterprise Institute) (pointing to biologics as the current driver of overall drug spending in the United States) [hereinafter Statement of Brill].

22 Statement of Brill, *supra* note 21 at 2.

drug prices,[23] shows the list price growth of brand-name pharmaceutical drugs decreased from 13.5% in 2014 to 4.2% in the first three quarters of 2020. In addition, net price growth declined -2.2% in 2020; the gross-to-net gap in prices was -6.4%.




The most important takeaway from this chart is that, by 2018, at least 90% of all prescriptions in the United States were filled with generic drugs, a trend attributed by some to "the concentration of purchasing power by payers and the aggressive use of utilization management tools to rapidly shift utilization towards generics."[24] Moreover, the price of certain generic drugs "more than doubled prices," including one from Exelan Pharmaceuticals, Inc. that treated high blood pressure "by 536% . . . depending on the dosage and package size."[25] In contrast, during the same year, pharmaceutical manufacturers raised prices by 6.6%, but even this increase did not allow those firms to "realize all or any of the benefit from price increases because of the discounts they provide to health insurers and pharmacy-benefit managers, the companies that oversee drug benefits for employers."[26]

---

[23] DRUG CHANNELS INST., https://drugchannelsinstitute.com/. The CEO of Drug Channels Institute, Dr. Adam J. Fein, Ph.D, is an expert in the U.S. pharmaceutical industry and a regular contributor to the *Wall Street Journal*, *The New York Times*, and *Forbes*. *Leadership*, DRUG CHANNELS INST., https://drugchannelsinstitute.com/about/leadership/.

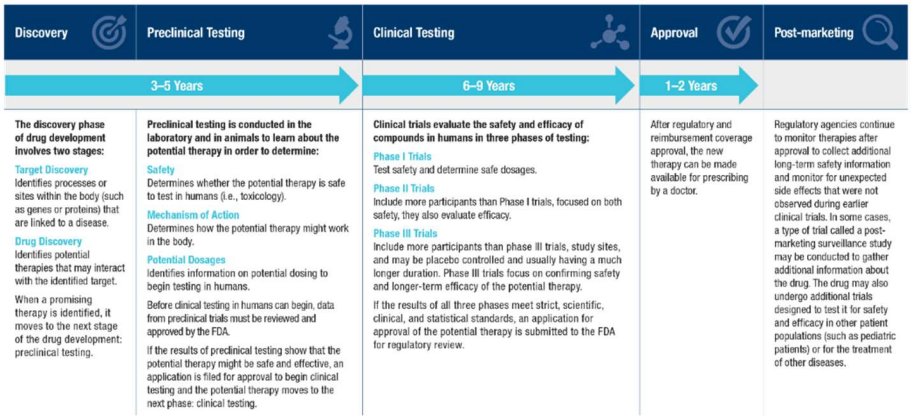
[24] *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition*, *Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 4 (May 7, 2019) (statement of James Stansel, Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America); *see also id.* at 6 (citing projections by IQVIA, a provider of analytics and clinical research services to the life sciences industry, that between 2019 and 2023, IQVIA estimates "annual net price growth for brand-name drugs will be just 0 to 3 percent.").

[25] Joseph Walker, *Prescription Drugs List Prices Rise Average of 6.6%*, WALL ST. J., Jan. 30, 2022, at A7.

[26] *Id.*; *see also*, Andrew Brownlee & Jordan Watson, *The Pharmaceutical Supply Chain, 2013–2020*, BERKELEY RSCH. GRP. (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/ ("Brand manufacturers retain just 37 percent of total spending on prescription

The Yale Article also gives short shrift to the time-consuming and expensive U.S. Food and Drug Administration (FDA) regulatory approval process.[27] As the following chart shows, this process can take many years, during which the twenty-year statutory term of a patent continues to run and while the patent holder receives no revenue.

Drug Development and Clinical Trial Process[28]




To address the time and cost of drugs receiving approval from FDA, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (informally known as the Hatch–Waxman Act)[29] to establish a "unified framework to coordinate drug approval and resolution of patent rights relating to generic versions of patented drugs."[30] On one hand, the Hatch–Waxman Act provides pharmaceutical patent owners with the potential for up to a five-year extension (restoration) on a patent's term, which is supposed to compensate patent owners for lost market opportunity.[31] The Act also provides for a data package exclusivity period, during

---

medicines (brand and generic medicines)."); *see also id.* ("2020 marks the first year on record where nonmanufacturer stakeholders—including PBMs, health plans, hospitals, the government, pharmacies, and others—received the majority of total spending on brand medicines."). PEW CHARITABLE TRS., THE PRESCRIPTION DRUG LANDSCAPE, EXPLORED 1 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf [hereinafter PEW CHARITABLE TRS.] (finding pharmaceutical manufacturer rebates increased from $39.7 billion in 2021 to $89.5 billion in 2016 only "partially offsetting increases in list prices"); *compare* PEW CHARITABLE TRS. at 14 (finding pharmaceutical manufacturers' net revenue on retail prescriptions grew only an average of 3.6% annually from 2012–2016), *with* PEW CHARITABLE TRS. at 14 (finding pharmacy net revenue on retail prescriptions increased from $30.8 billion to $76.9 billion in 2016); Letter from Senator Thom Tillis to Janet Woodcock, MD, Acting U.S. Food & Drug Comm'r and Drew Hirshfeld, Acting Comm'r for Patents (Jan. 31, 2022) (questioning the accuracy of drug price research from the Initiative for Medicine, Access & Knowledge and a project from the University of California Hastings Law School); Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, HUDSON INST. (Jan. 19, 2022).

[27] *See* 21 U.S.C. § 355(a)–(b) (2012).

[28] *See Drug Development, Review & Lifecycle Management*, BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/policy/human-health/drug-development-review-lifecycle-management.

[29] *See* Pub. L. No. 98-417, 98 Stat. 1585(1984) (codified at 21 U.S.C. § 30; 21 U.S.C. §§ 355, 360cc).

[30] FEDERAL JUDICIAL CENTER, PATENT CASE MANAGEMENT 10-2 (3d ed. 2016).

[31] A study conducted of 170 top-selling drugs which had a first generic equivalent approved between 2000–2012, found that only 49% (or eighty-three drugs) received a patent term restoration. The median

which a generic manufacturer is prohibited from referencing any proprietary regulatory data of a pharmaceutical "originator" for five years in pursuit of obtaining FDA approval for a competing drug.[32] On the other hand, after this period expires, a generic manufacturer can accelerate approval for a "follow-on" drug, if it is the "bioequivalent" of a patented drug, among other criteria.[33] As a prerequisite, the generic manufacturer must file an Abbreviated New Drug Application (ANDA) and a statement certifying the patents that claim the listed drug have expired, will expire, are invalid, unenforceable, or will not be infringed (or there are no listed patents).[34] Next, if the generic manufacturer wants to market its product prior to the expiration of a patent, it must provide the "originator" with notice and certification attesting to the same requisites as the ANDA filing.[35] Then, an "originator" has forty-five days in which to lodge an infringement action challenging the certification in a federal district court, thereby triggering an automatic thirty-month stay of FDA's approval of the ANDA.[36] During the stay, FDA may not approve the ANDA unless: the patent expires; a federal district court determines the "originator's" patent is invalid, unenforceable, or not infringed; or the thirty-month stay expires, whichever comes first.[37]

After the Yale Article was published, the Technology Law & Policy Clinic of New York University School of Law, co-published with PrEP4All, released a student publication (NYU Student White Paper), parroting the same rhetoric: "[P]atents permit [pharma] companies to set and keep prices astronomically high—much higher than needed to fund future drug development, and much, much higher than the manufacturing cost."[38] Like the Yale Article, the NYU Student White Paper, cites no empirical data to support the assertion that pharmaceutical prices exceed costs incurred to conduct research, develop, and obtain a patent, or much less garner FDA approval to manufacture, market, and distribute a pharmaceutical drug and then educate the

---

extension length was only 2.75 years. *See Unsustainable Drug Prices (Part III), Hearing Before the H. Comm. on Oversight and Reform*, 117th Cong. (2021) (statement of Dr. Aaron S. Kesselheim, Professor of Medicine, Harvard Medical School and Director, Program on Regulation Therapeutics and Law, Department of Medicine, Brigham and Women's Hospital (citing Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *Patent Term Restoration for Top-selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20–25 (2019).

[32] 21 U.S.C. 355 § (3)(ii)–(iv).

[33] *See id.* § 355(j)(4)(F) ("bioequivalence" requires a generic manufacturer to demonstrate its drug delivers approximately the same amount of active ingredients into the bloodstream as the same amount of the reference drug).

[34] These drugs are listed in an annual FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. *Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book. *See* 21 U.S.C. §§ 355(b)(2)(A)(ii)–(iv), (j)(2)(A)(vii)(IV).

[35] *See id.* §§ 355 (b)(3)(C), (j)(2)(B)(iii).

[36] *See id.* §§ 355(c)(3)(C), (j)(5)(B)(iii); *see also* 35 U.S.C. § 271(e)(2).

[37] *See* 21 U.S.C. § 355(j)(5)(B)(iii)(1); *see also id.* § 355 (c)(3)(C)(i).

[38] JOSEPH ADAMCZYK, ADRIENNE LEWIS & SHIVANI MORRISON, N.Y.U. TECH. L. & POL'Y CLINIC, § 1498: A GUIDE TO GOVERNMENT PATENT USE: A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS (2020–2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/60099e3582c53f4f1b6a4a57/1611243061897/P4A++1498+A+Guide+to+Government+Patent+Use.pdf%22%20%5Ct%20%22_blank; *Id.* at 9.

medical community and patients about a new drug.[39] It is well established, however, that "[i]t takes on average over 2 billion dollars and close to 10 years of R&D, at a 90% failure rate, before a new investigational drug can be approved and made available for patient care."[40] The authors of the NYU Student White Paper tout the "versatility" of Section 1498(a), as "leverage" the government can use in negotiating pharmaceutical prices, by assuming "reasonable and entire compensation generally will be less than the cost of acquiring the patented technology on the open market—sometimes significantly so."[41] The NYU Student White Paper, however, cites no empirical data to support the authors' contention that Section 1498(a) damages for infringement of pharmaceutical patents will be less than paying for a license or that it "generally reimburses the patent holder for the fair market value of the patent rights over the life of the patent."[42]

Another reckless idea of the NYU Student White Paper suggests, if an "originator" files a Hatch–Waxman Act case against a generic manufacturer in a federal district court, HHS promptly should license the generic to infringe the pharmaceutical patent.[43] The NYU Student White Paper then recommends HHS intervene in the Hatch–Waxman case to seek dismissal and transfer the case to United States Court of Federal Claims under Section 1498(a), effectively divesting the pharmaceutical "originator" of the Hatch–Waxman Act thirty-month automatic stay.[44] This scenario would have an Executive Department interfere with a Hatch–Waxman action authorized by Congress and should be rejected by a federal court as a violation of the Administrative Procedure Act (APA),[45] not to mention raising separation of powers

---

[39] Letter from Drew Hirshfeld, Acting Comm'r for Patents to Senator Elizabeth Warren and Congresswoman Pramila Jayapal 9–10 (Aug. 13, 2021) ("Developing the dossier of data necessary to obtain marketing approval for a new drug or biologic product in the U.S. is a complex, lengthy, and very costly endeavor, often taking years to complete[.] In 2020, HHS's Center for Drug Evaluation and Research reported than a total of just 53 'novel drugs' were approved."); *see also* Dr. Eric Topol, *The Hyper-Acceleration of the Life Sciences*, WALL ST. J., Mar. 19, 2021, at C4 ("[T]he average time in the life sciences for translating research into clinical practice is 17 years . . . . The successful mRNA vaccines that set such a high bar of efficacy and safety so early in the pandemic were not conceived in 2020. The use of mRNA was pioneered in the basic research of Katalin Karikó and Drew Weissman at the University of Pennsylvania three decades ago.").

[40] Letter from James C. Greenwood, President and CEO, Biotechnology Innovation Organization, Letter to Alex M. Azar, Secretary, U.S. Dep't of Health & Hum. Servs. 2–3 (Mar. 12, 2018); *see also Unsustainable Drug Prices (Part III), Hearing Before the H. Comm. on Oversight and Reform*, 117th Cong. 5 (2021) (statement of Dr. Carl L. Garthwaite, Herman Smith Research Professor in Hospital and Health Care Services Management and Director of Program on Healthcare at the Kellogg School of Management, Northwestern University) ("The development of pharmaceuticals is a long and risky process where firms make investments that only expect to payoff [sic] over a potentially decades long time horizon.") [hereinafter Statement of Garthwaite]; Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) (estimating $2.87 billion in "capitalized cost" (2013 dollars) to bring a new drug to market).

[41] ADAMCZYK ET AL., *supra* note 38, at 24.

[42] *Id.*

[43] *Id.* at 34.

[44] *Id.*

[45] *See* 5 U.S.C. § 706(2)(A) (federal agency action is subject to judicial review under, among others, an "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law" standard); *see also* Motor Vehicle Mfg. Ass'n v. State Farm Auto Mut. Ins. Co., 463 U.S. 29, 43 (1983) (emphasis added) (stating that a federal agency's decision is *arbitrary*, if it "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation

issues. In the alternative, having the HHS Secretary contract with a generic to infringe a pharmaceutical patent or intervening *sua sponte* in a Hatch–Waxman case to deprive a patent holder of the thirty-month automatic stay granted by Congress could be well viewed by a federal court as unlawful because it is "not one of those areas traditionally committed to agency discretion."[46]

A particularly problematic suggestion of the NYU Student White Paper is for the government "to coordinate with generic manufacturers to work around . . . non-patent exclusivities."[47] Generic manufacturers that engage in "coordinating" price or supply, however, risk violating the antitrust law and facing private treble damage actions.[48]

## III. FEDERAL COURTS SHOULD HOLD THAT SECTION 28 U.S.C. § 1498(A) IS NOT APPLICABLE TO GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS TO REDUCE DRUG PRICES

The Yale Article also proclaims: "28 U.S.C. § 1498[(a)] permits the government to 'use' patents at any time without permission of the patent holder, as long as reasonable compensation is provided."[49] Not quite.

In 1949, Congress amended 28 U.S.C. § 1498 to clarify the parameters of the waiver of sovereign immunity in the event the government infringed a patent:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture . . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.[50]

The first federal appellate court to consider Section 1498(a) held:

---

for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

[46] Dep't of Com. v. New York, 139 S. Ct. 2551, 2568 (2019); *see also* Liesegang v. Sec'y of Veterans Affs., 312 F.3d 1368, 1372 (2002) ("This court reviews questions of statutory interpretation without deference.").

[47] ADAMCZYK ET AL., *supra* note 38, at 3.

[48] 15 U.S.C. § 1 (*prohibiting* "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States"); *see also* 15 U.S.C. §15(a) ("[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States[.];") 15 U.S.C. § 15c (authorizing state Attorneys General to file federal antitrust actions on behalf of their citizens).

[49] Brennan et al., *supra* note 2, at 279–80.

[50] *See* 28 U.S.C. § 1498.

> Nowhere [therein] is active inducement of infringement or contributory infringement mentioned, either directly or by cross reference to 35 U.S.C. §§ 271 (b) and (c). ***A waiver of sovereign immunity must be strictly construed.*** Stated differently, the Government is not to be regarded as having waived its sovereign immunity by implication. Hence, we hold that 35 U.S.C. §§ 271 (b) and (c) are not incorporated by implication in section 1498. It is our view that the ***Government has agreed under section 1498 merely to assume liability for its direct infringement of a patent; it has not agreed thereunder to assume liability for its active inducement of infringement or for its contributory infringement***.[51]

The strict application of Section 1498(a) has not changed over the years and, in the last decade, was reaffirmed en banc by the United States Court of Appeals for the Federal Circuit (Federal Circuit).[52]

The statutory term "use for the Government" has two elements: "use that is both 'for the Government' *and* 'with the authorization and consent of the Government.'"[53] Nevertheless, the Yale Article states "where the infringing party has shown that they are acting pursuant to a contract with the federal government, courts typically assume use 'for' the government without further inquiry."[54] The Federal Circuit, however, has been clear that this analysis is incorrect.[55] Instead,

> use "for the United States" is defined as use that is both "for the Government" and "with the authorization and consent of the Government." In context, the "for the Government" prong of the definition appears to impose only a requirement that the use or manufacture of a patented method or apparatus occur *pursuant to a contract with the government* and for the benefit of the government.[56]

Nevertheless, the Yale Article insists that the two separate elements of Section 1498(a) can be conflated as "government use,"[57] citing three cases where the Federal Circuit held Section 1498(a) applied.[58] Each of these cases is *sui generis* and the analysis of questionable precedential effect.

In the first case, the government's participation in the Skynet satellite program was found to be "for the Government's benefit" because the program was considered "critical" to the military defense and security of the United States.[59] Military defense

---

[51] Decca Ltd. v. United States, 640 F.2d 1156, 1169–70 (Ct. Cl. 1980) (emphasis added).

[52] Zoltek Corp. v. United States, 672 F.3d 1309, 1320 (Fed. Cir. 2012) (en banc) ("The court [in *Decca*] explained that inducement and contributory infringement are outside § 1498(a) because they 'do not involve *the Government's* making or using a patented invention[.]'") (emphasis in original) (quoting *Decca*, 640 F.2d at 1170 & n.31).

[53] Sevenson Envt'l Servs., Inc. v. Shaw Envt'l, Inc. 477 F.3d 1361, 1365 (Fed. Cir. 2007) (emphasis in original).

[54] Brennan et al., *supra* note 2, at 333.

[55] *Sevenson Envt'l Servs., Inc*., 477 F.3d at 1365.

[56] *Id.* (underscore in original, emphasis added).

[57] Brennan et al., *supra* note 2, at 332.

[58] *Id.* at 332 n.266; *see also id.* at 333 nn.269, 272.

[59] Hughes Aircraft Co. v United States, 534 F.2d 889, 898 (Ct. Cl.1976).

and national security, however, are not at issue in the event the government infringes a pharmaceutical patent.

The second case involved an airline's use of a patent that improved the detection of fraudulent passports and reduced demands on government resources.[60] The infringing use was viewed as a "quasi-governmental function" and "for the Government's benefit" since a federal entity otherwise would be required to examine passports for fraud.[61] In addition, this use was found to be "in furtherance and fulfillment of a stated Government policy," i.e., "enhances border security and improves the government's ability to monitor the flow of people in and out of the country."[62] Government infringement of a pharmaceutical patent certainly is not a "quasi-governmental function."

In the third case, a Federal Reserve Bank entered a contract with a private company to use its encoded technology in a pilot project to ferret out fraudulent checks.[63] The Treasury Department participated in the project by printing checks that used the encoded technology. It turned out this technology violated another company's patent. The Federal Circuit was satisfied that this was "use for the Government," even though there was no contract with Treasury, based on the involvement of two federal agencies, "reinforced by" a government amicus in a private Title 35 case attesting that Treasury's "use" was "for the Government."[64] The appellate court also seemed impressed that the infringing activity conferred "significant benefits to the United States," although the record below on this issue was not fully developed.[65]

The second element of Section 1498(a), i.e., "the scope of the government's authorization and consent to liability naturally hinges on the language of that clause."[66] Today, most government contracts contain "authorization and consent" clauses. For example, supply contracts routinely incorporate Federal Acquisition Regulation (FAR) 52.227-1 authorizing contractors or subcontractors to "use and manufacture" a patented invention where it is 1) embodied in the structure or composition of any article delivered to and accepted by the government related to a government contract; or 2) used in machinery, tools, or methods necessary for a contractor to comply with the Specifications of a contract, or if such use is directed by a contracting officer's specific written instructions. Research and development contracts include FAR 52.227-1 Alternative I to express "authorization and consent" in the event of patent infringement. "Authorization and consent" also have been found "by contracting officer instructions, by specifications and drawings which impliedly sanction and necessitate infringement, or by *post hoc* intervention by the Government in pending infringement litigation against individual contractors."[67]

---

[60] Iris Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1362 (Fed. Cir. 2014).

[61] *Id.* at 1362–63 (stating the government's amicus "reinforce[d] [the court's] conclusion that the United States has waived sovereign immunity in this case").

[62] *Id.* at 1362.

[63] Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis, 583 F.3d 1371, 1376–79 (Fed. Cir. 2009).

[64] *Id.*

[65] *Id.*

[66] *Id.* at 1367.

[67] Hughes Aircraft Co. v United States, 534 F.2d 889, 901 (Ct. Cl.1976).

The Federal Circuit has considered only one case where it found "implied authorization and consent" without a government contact.[68] There, a bidder for a government contract was required to provide a "specimen" of equipment and a live demonstration to show its ability to perform if it were awarded a contract.[69] Since the government was aware this requirement would infringe another bidder's patent, the appellate court was satisfied that this evidenced sufficient "authorization and consent" to invoke Section 1498(a).[70] The equitable issues presented in that case, however, are far different from government infringement of a pharmaceutical patent.

More importantly, as a matter of law, if the government infringes a pharmaceutical patent to reduce Medicare and Medicaid costs, Section 1498(a) will not apply. This is so because the predecessor to the United States Court of Appeals for the Federal Circuit soundly rejected a medical device company's Section 1498(a) claim that selling infringing splints was "for the benefit of the Government," even though their costs were reimbursed under Medicare and other federal programs.[71] Notably, the court's holding emphasized the fact that the government has an "interest in [a] program generally, or funds or reimburses all or part of its costs, is *too remote* to make the government the program's beneficiary for the purposes underlying §1498."[72] Clearly, the court recognized that, if every federal program is deemed to be "for the Government," there would be no end to cases asserting Section 1498(a)—a statute to be construed "strictly."[73] Likewise, government infringement of a pharmaceutical patent could be viewed as "not the type of activity that Congress, by enacting Section 1498(a), intended to cloak with immunity from injunction."[74] This reasoning is akin to the Supreme Court's recent invocation of the "major questions" doctrine to invalidate "agencies asserting highly consequential power beyond what Congress

---

[68] TVI Energy Corp. v. Blane, 806 F.2d 1057 (Fed. Cir. 1986).

[69] *Id.* at 1059.

[70] *Id.* at 1060.

[71] Larson v. United States, 26 Cl. Ct. 365, 369 (1992).

[72] *Id.* (emphasis added); *see also* MATTHEW RIZZOLO, FILKO PRUGO, CHARLOTTE JACOBEN, RYAN SULLIVAN & BRENDAN MCLAUGHLIN, ROPES & GRAY LLP, CAN THEY REALLY DO THAT? THE SPECTER OF GOVERNMENT-AUTHORIZED INFRINGEMENT OF PHARMACEUTICAL PATENTS 8 (Apr. 27, 2020), https://www.ropesgray.com/en/newsroom/alerts/2020/04/Can-They-Really-Do-That-The-Specter-of-Government-Authorized-Infringement-of-Pharmaceutical-Patents ("Medicaid is primarily run by the states, with complex systems of rebates and reimbursements for prescription drugs, and Medicare provides outpatient prescription drugs though Medicare Part D private insurance. Because of the [federal] government's indirect role in these programs, . . . any use of § 1498 would likely rest on uncertain legal ground[.]").

[73] Decca Ltd. v. United States, 640 F.2d 1156, 1169 (Ct. Cl. 1980).

[74] Carrier Corp. v. United States, 534 F.2d 244, 250 (Ct. Cl. 1976). A recent decision echoes this concern, where the District Court of Delaware denied a partial motion to dismiss a case asserting that any royalties on the sale and provision of COVID-19 vaccine doses to the United States were governed by 28 U.S.C. § 1498(a) and therefore subject to the jurisdiction of the United States Court of Federal Claims. *See* Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al., Case No. 22-252, slip op. (D. Del. Nov. 22, 2022). Notably, the court found "this case more akin to Larson than Advanced Software Design[.] Based on the allegations of the Complaint, which I must accept as true, the development and sale of the vaccines was for the benefit of the vaccine's recipients. According to the Complaint, the U.S. Government was an incidental beneficiary who borne an interest in ensuring the safety of its citizens." *Id.* at 12. The court also rejected argument that inclusion of FAR 52,227-1 in the contract was dispositive evidence of "authorization and consent" of the government as, "it remains unsettled whether the Government, in seeking to hasten the development of a vaccine, actually consented to the use of a patented invention and agreed to accept any liability for such use." *Id.* at 15. Obviously, the final disposition of this case bears watching.

could reasonably understood to have granted."[75] Therefore, government infringement of a pharmaceutical patent should be struck down on that basis, particularly since the effect would be to divest a patent owner of a property right conveyed by the USPTO, without a judicial determination of invalidity.[76]

Nevertheless, the Yale Article proposes that HHS, *sua sponte*, announce the names of the patented pharmaceutical drugs it intends to displace,[77] so that federal procurement officers can proceed to contract directly with generic manufacturers. The Yale Article concedes that the government will be obliged to offer pharmaceutical patent owners "modest or nominal compensation," such as a royalty on the price of the generic.[78] The Yale Article adds, if a pharmaceutical patent owner is not satisfied, it can file an administrative claim or suit under 28 U.S.C. § 1498(a).[79] The Yale Article naively envisions this process would be "legally uncontroversial" and "quickly implemented,"[80] without considering that government infringement of a pharmaceutical patent would require the Federal Circuit to overrule precedent *en banc* and, even if that happened, a petition for certiorari to the United States Supreme Court would be inevitable. And, as we next discuss, if government infringement of a pharmaceutical patent were able to satisfy the elements of Section 1498(a), multi-million-dollar damage awards likely will result.

## IV. IF GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS IS SUBJECT TO SECTION 1498(A), AMERICAN TAXPAYERS WILL ULTIMATELY FOOT THE BILL FOR MULTI-MILLION DOLLAR DAMAGE AWARDS

The rationale for Section 1498(a) is not complicated. As the predecessor to the Federal Circuit explained: "[the Government] is deemed to have 'taken' the patent license under an eminent domain theory, and compensation is the just compensation required by the fifth amendment. Title 28 U.S.C. § 1498 *contains no directions or limitations as to the grant of damages* other than its mandate of 'reasonableness' and 'entirety.'"[81] In other words, "reasonable compensation" should equate to "what the owner has lost, not what the taker has gained."[82] As Justice Breyer has observed,

---

[75] In light of the Supreme Court's recent decision in *West Virginia v. EPA*, whether the government, via the HHS Secretary, can deny or shorten a pharmaceutical patent owner's statutory right to exclude competition for a limited time period and/or divest a pharmaceutical patent owner of the exclusivities granted by Congress under the Hatch–Waxman Act, without explicitly repealing that statute, may well be considered by a federal appellate court as under the "major question doctrine" in light of the "economic and political significance" of such executive action, instead of conducting an APA review. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2609 (2022).

[76] *See id.* at 20; *see also* 35 U.S.C. §§ 282(a), (b)(2) (reflecting congressional intent that all patents are presumed to be valid, unless a federal court determines otherwise).

[77] Brennan et al., *supra* note 2, at 346 (This scenario is suggested for HCV drugs but is "common to all options of our § 1498 strategy."); *see also id.* at 282 (suggesting the government also should "import" generic drugs from a foreign country "maximizing social benefit").

[78] *Id.* at 347.

[79] *Id.*

[80] *Id.*

[81] Leesona Corp. v. United States, 599 F.2d 958, 964 (Ct. Cl. 1979) (emphasis added).

[82] *Id.* at 969 (citing United States v. Chandler-Dunbar Co., 229 U.S. 53, 76 (1913).

"patent infringement suits against the Government . . . threaten to impose large damage awards."[83]

The Federal Circuit has endorsed three methods for determining "reasonable compensation": a reasonable royalty; government savings achieved by use of an infringed patent; or the patent owner's lost profits,[84] although the latter two methods primarily have been used to evaluate the "reasonableness" of royalty awards.[85]

For many years, Section 1498(a) damages have been determined by federal trial judges evaluating and balancing the same factors as private patent infringement cases under 35 U.S.C. § 271.[86] The Federal Circuit, however, has expressed concern about using these factors to determine an appropriate royalty rate describing them as "[a] comprehensive (but unprioritized and often overlapping) list of relevant factors for a reasonable royalty calculation."[87] Shortly thereafter, the appellate court also rejected the past practice of using a "rule of thumb" approach to determine a "reasonable royalty rate."[88] Consequently, most trial judges now set a "reasonable royalty" either at a rate that is comparable to prior license terms or by replicating an arms-length negotiation.[89] Two caveats: the Federal Circuit has rejected royalty rates where the license was not specifically "linked" to an infringed product.[90] The appellate court also has rejected license terms entered after litigation was threatened or underway.[91]

Where an infringed patent previously has not been licensed, determining a "reasonable royalty" has been described as "a difficult judicial chore, seeming often

---

[83] Return Mail, Inc. v. U.S. Postal Serv., 139 S. Ct. 1853,1871 (2019) (Breyer, J., dissenting).

[84] *Leesona Corp*., 599 F.2d at 964.

[85] *Id.* at 973.

[86] Gargoyles, Inc. v. United States, 113 F.3d 1572, 1580–81 (Fed. Cir. 1997) (citing fifteen factors listed in Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and affirmed sub. nom*, Ga-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc., 446 F.2d 295, 302 (2d Cir. 1971).

[87] ResQNet.com, Inc. v. Lansa, Inc., 594 F.3d 860, 869 (Fed. Cir. 2010); *see, e.g.*, Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages*, 2010 BYU L. REV. 1661, 1726 (2010) (concluding that the *Georgia-Pacific* test has "outlived its usefulness" and "is no meaningful standard at all"); Stuart Graham, Peter Menell, Carl Shapiro & Tim Simcoe, *Final Report of the Berkeley Center for Law & Technology Patent Damages Workshop*, 25 TEX. INTEL. PROP. L.J. 115, 117 (2016).

[88] Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1315 (Fed. Cir. 2011) (holding "the 25 percent rule of thumb is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation. Evidence relying on the 25 percent rule of thumb is inadmissible under *Daubert* and the Federal Rules of Evidence, because it fails to tie a reasonable royalty base to the facts of the case at issue.").

[89] *Leesona Corp*., 599 F.2d at 973. ("The comparative royalty technique is the preferred method of determining just compensation."); *see also* Unisplay S.A. v. Am. Elec. Sign Co., Inc., 69 F.3d 512, 519 (Fed. Cir. 1995) (existing licenses "carry considerable weight in calculating a royalty rate").

[90] Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1327–28 (Fed. Cir. 2009) (rejecting reliance on licenses that were "radically different from the hypothetical agreement under consideration"); *See also* Trell v. Marlee Elecs. Corp., 912 F.2d 1443, 1446 (Fed. Cir. 1990) (rejecting licenses that "conveyed rights more broad in scope than those covered by the [infringed] patent").

[91] Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1078–79 (Fed. Cir. 1983) ("license fees negotiated in the face of a threat of high litigation costs may be strongly influenced by a desire to avoid full litigation"); *see also* Nickson Indus., v. Rol Mfg. Co., 847 F.2d 795, 798 (Fed. Cir. 1988) (stating a higher figure may be awarded when evidence shows that established royalties are artificially depressed by widespread infringement).

to involve more the talents of a conjurer than those of a judge."[92] Therefore, trial courts typically use the "entire market rule" to ascertain a compensation base that reflects "the value of an entire apparatus containing several features, when the feature patented constitutes the basis for customer demand."[93] Once a compensation base is determined, an appropriate royalty rate is determined considering what would happen in a hypothetical license negotiation between a willing seller and willing buyer. In reviewing various negotiation scenarios, the Federal Circuit also has allowed trial courts to consider a range of royalty rates, if supported by credible expert testimony.[94]

The Federal Circuit also has endorsed determining "reasonable compensation" by having the trial court construct a hypothetical "ceiling" and "floor," within which the royalty rate will be deemed "reasonable."[95] In that case, the "ceiling" was set as the total savings difference "between what it paid [an infringing government contractor]" and the patent owner's price.[96] The "floor" was set as the "reasonable" development expenses incurred,[97] amortized over the life of the patent and also a "reasonable profit."[98] In this case, the royalty rate also included the "special value of the exclusive manufacturing rights, their importance to the diversification plans [of the patent owner], made their worth much greater and thus the hypothetical royalty charged would have been . . . higher."[99] Therefore, if the government infringes a pharmaceutical patent, the damage "ceiling" could equal the government's estimated total savings achieved by infringing the pharmaceutical patent[100] and the "floor" could equal the pharmaceutical company's reasonable amortized development costs and the "claimed invention's foot print in the marketplace"[101] or "commercial success."[102] The

---

[92] Fromson v. W. Litho Plate & Supply Co., 853 F.2d 1568, 1574 (Fed. Cir. 1988).

[93] TWM Mfg., Co. v. Dura Corp. 789 F.2d 895, 901 (Fed. Cir. 1986); *see also* Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1549 (Fed. Cir. 1995) (en banc) (The entire market rule "permits recovery of damages based on the value of a patentee's entire apparatus containing several features when the patent-related feature is the basis for customer demand.").

[94] Bayer HealthCare LLC. V. Baxalta, Inc., 989 F.3d 964, 983 (Fed. Cir. 2021) (holding damages may be determined within a "range of possible hypothetical negotiation royalty rates[; however,] we are aware of no precedent that requires an expert to provide a single proposed royalty rate").

[95] Leesona Corp. v. United States, 599 F.2d 958, 977–78 (Ct. Cl. 1979).

[96] *Id.* at 977.

[97] *Id.*

[98] *Id.*

[99] *Id.* at 978.

[100] *Id.* at 971 ("Savings to the government may be considered in determining reasonable and entire compensation. Its most proper use [however] . . . is in estimating what royalty willing buyers and sellers would agree to.").

[101] ResQNet.com, Inc. v. Lansa, Inc., 594 F.3d 860, 869 (Fed. Cir. 2010). *See also* Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1350 (Fed. Cir. 1999) ("To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture.").

[102] Rahul Guha, Jian Li & Andrea L. Scott, *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1:5 LANDSLIDE 8, 13 at n.10 (May/June 2009) ("The level and growth of sales as a share of sales by competing drugs is another important indicator of commercial success because it speaks to the success of the product relative to its competitors . . . . Pricing of the drug relative to competing drugs may also be a relevant indicator of commercial success. In particular, the ability to command a price premium over other competing drugs and still enjoy sales and share growth suggests that a drug provides unique therapeutic benefits. Other possible indicators of a drug's commercial success include rapid and widespread international diffusion and widespread favorable coverage for the drug in prescription drug plans."); *see*

resulting damage award in a Section 1498(a) case involving government infringement of a pharmaceutical patent using this analysis would no doubt be significant.

In contrast, the Yale Article proposes that federal trial judges in Section 1498(a) cases should determine "reasonable compensation" by "establishing a baseline reasonable royalty calculated as a percentage of the generic drug price."[103] No case supports finding a "reasonable royalty" based on a competitor's price which necessarily will entail discovery about R&D, manufacturing, distribution, sales costs, and profit allocation. The Yale Article further suggests, if appropriate evidence is proffered by the patent owner, the trial court could simply "adjust this compensation award upwards to account for the patentee's risk-adjusted R&D costs and to ensure a reasonable profit."[104] Of course, the Yale Article does not explain how a pharmaceutical manufacturer's "risk-adjusted R&D costs" would be determined, although we assume it would exclude the value of any unexpired patent term.[105] Nor does the Yale Article consider that calculating a "reasonable profit" for a pharmaceutical drug necessarily requires extensive discovery and necessarily be a highly subjective exercise.[106]

In the alternative, the Yale Article surmises that a "residual royalty" could be determined by a generic manufacturer's earnings, even though this likely would result in a "very low baseline."[107] To solve this problem, the Yale Article envisions that the trial judge could just "gross up" the "residual royalty" by some arbitrary amount to "ensure adequate incentives for innovation."[108] In determining the "gross up," the Yale Article assures us that "courts need not make these calculations perfectly: even with a sizable margin of error, the social gains in these cases will likely far exceed the possible losses."[109] There is absolutely no basis in case law for the federal courts to dispense what amounts to Robin Hood-type justice.

A more reliable way to measure damages for government infringement of a pharmaceutical patent would be lost profits, i.e., multiplying the units of the generic drugs sold by the profit margin of the infringed patented drug.[110] Although the appellate court initially was skeptical of awarding lost profits as damages in Section

---

*also id.* at 9–10 ("Commonly used indicators of commercial success, include significant sales levels, significant sales growth, price premiums, and other indicators. Pharmaceutical sales can be measured by dollars of sales revenue, prescriptions, or daily doses.").

[103] Brennan et al., *supra* note 2, at 283.

[104] *Id.*

[105] *Leesona Corp.*, 599 F.2d at 979 ("Although we can and do heavily stress the importance of exclusivity when determining the applicable royalty rate, we cannot say that § 1498 provides compensation for its loss independently of the statutory defined bases for compensation.").

[106] Guha et al., *supra* note 102, at 10 (Determining profitability by the return of invested capital to discover and develop drugs "is difficult to obtain because R&D costs may be incurred over a long period of time and may not easily be allocated to a particular drug. In addition, a lack of positive return on capital investment should not necessarily undermine a conclusion of commercial success. A few 'blockbuster' drugs generate the majority of profits for the drug companies. That means the majority of smaller drugs may not be profitable in the sense of recouping all the costs of their discovery and development, even if they have therapeutic value.").

[107] Brennan et al., *supra* note 2, at 315.

[108] *Id.*

[109] *Id.* at 282.

[110] Guha et al., *supra* note 102, at 10 ("Because pharmaceuticals have low production costs, sales revenue is a good proxy for gross profitability.").

1498(a) cases,[111] that is no longer so.[112] Even, the Yale Article agrees that lost profits are an appropriate measure of damages if the government infringes pharmaceutical patents and suggests what it describes as a "10 to 30% bounty [to] approximate average profits in the pharmaceutical industry."[113] Anticipating a negative public reaction to what would be a significant damage award, the Yale Article informs us: "[C]ourts must play a role in setting damages. That role might, however, be merely a backstop. Agencies can establish guidelines that will shape any bargaining around the courts' powers, thereby influencing courts' calculations and reducing uncertainty about how courts would assess damages."[114] The Federal Circuit certainly would not allow an agency's "guidance" to trump the primacy of the courts in assessing patent infringement damages: "[G]uidance 'is not, itself, the law . . . , does not carry the force of law, and is not binding on our . . . analysis.' And to the extent the guidance 'contradicts or does not fully accord with our caselaw [sic], it is our caselaw [sic], and Supreme Court precedent it is based upon, that must control.'"[115]

Nevertheless, the Yale Article claims its damage analysis is "[i]n line with the goals of § 1498 and patent protection more broadly, [as] our proposed compensation methodology tethers patent compensation to the risk-adjusted costs of innovation."[116] It is difficult to imagine how government infringement of patents can be conceived as a "goal of patent protection." In addition, the Yale Article's view that the "goal of patent protection" is to provide "compensation" for "the risk-adjusted cost of innovation" appears nowhere in the text of patent law nor any judicial decision that the authors have identified. Moreover, the Yale Article fails to acknowledge that the United States, unlike other developed countries, heavily relies on private markets to finance pharmaceutical research and development,[117] as the following chart shows.[118]

---

[111] Tektronix, Inc. v. United States, 552 F.2d 343, 348–49 (Cl. Ct. 1997), *opinion modified on denial of remand*, 557 F.2d 265 (Cl. Ct. 1977) (ruling that when the federal government is the infringer, lost profits must be established by the "strictest proof").

[112] Leesona Corp. v. United States, 599 F.2d 958, 971 (Ct. Cl. 1979) ("[O]ur suggestion in *Tektronix* [was] lost profits might be used in some circumstances to measure just compensation.") *See also* Gargoyles, Inc. v. United States, 113 F.3d 1572, 1576 (Fed. Cir. 1997) ("[L]ost profits should be recoverable in at least some infringement actions against the government[.]").

[113] Brennan et al., *supra* note 2, at 315; *see also id.* at 284, n.35 (citing Liyan Chen, *Best of the Biggest: How Profitable Are the World's Largest Companies*, FORBES (May 13, 2014)); *see also id.* at 315 n.196; *see also* Guha et al., *supra* note 102, at 10 ("Because pharmaceuticals have low production costs, sales revenue is a good proxy for gross profitability.").

[114] *Id.* at 326.

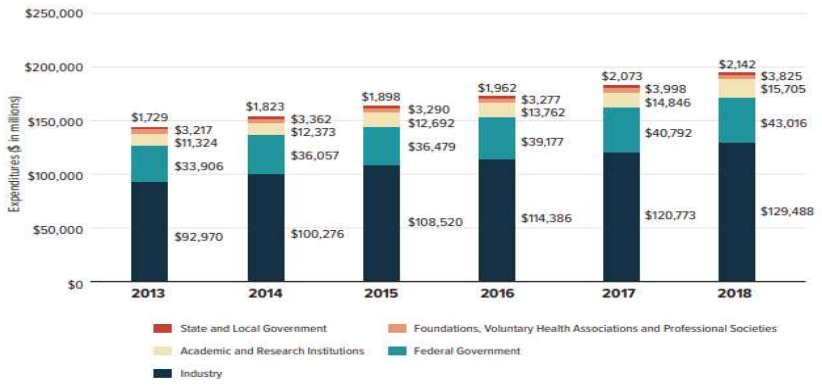
[115] cxLoyalty, Inc. v. Maritz Holdings, Inc., 986 F.3d 1367, 1375, n.1 (Fed. Cir. 2021) (citation omitted).

[116] Brennan et al., *supra* note 2, at 353.

[117] *See* Statement of Garthwaite, *supra* note 40, at 2 ("In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. While this is a source of consternation for some, this use of economic markets is not a policy accident and instead reflects a belief that there are many advantages to market-based healthcare. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services.").

[118] *See* RESEARCH!AMERICA, U.S. INVESTMENTS IN MEDICAL AND HEALTH RESEARCH AND DEVELOPMENT 2013–2018 5 fig. 3 (2019).

**Figure 3:** Estimated U.S. Medical and Health R&D Expenditures ($ in millions), 2013-2018




5 Research!America

Numerous life-saving drugs have been brought to market as a result of private investment in the pharmaceutical industry.[119] A recent example is ABECMA™, a cell therapy developed by Bristol-Myers Squibb Co. and bluebird bio, Inc., with great promise in curing multiple myeloma where other drugs have not worked.[120] This therapy collects patient T cells that are sent to a laboratory where specialized molecular hooks are inserted into the T cells. The T cells are then reinjected into the patient where they attach to a marker found in cancerous cells.[121] After 2017, when this therapy was approved by FDA, venture capital contributed over $3.83 billion to accelerate availability to the public, even though new competitors already were on the scene.[122] Although the initial wholesale price of a one-time infusion was $419,500, that cost is expected to be reduced and covered by Medicare and commercial insurers.[123] To be sure, this still will be an expensive therapy, but previously there was no cure for multiple myeloma.

Another example is LUMAKRAS™, a pill developed by Amgen, Inc., which treats a genetic mutation found in lung cancer. This drug received FDA approval in May 2021, having "sped through clinic trials since the first encouraging results in 2019."[124] About 13% of patients with non-small cell lung cancer, or approximately 25,000 individuals annually, now have a drug where previously no treatment was available.[125] It is expected that LUMAKRAS™ will cost $17,900 a month, but its commercial success will depend on whether it works either as a first-line treatment or in

---

[119] *Id.* at 5 (reporting that in 2018, the biopharma industry spent approximately $129.5 billion or 66.7% of all such R&D expenditures).

[120] Brian Gormley, *Cancer Therapies Draw Venture Cash*, WALL ST. J., May 14, 2021, at B11.

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] Joseph Walker, *Amgen's Lung Cancer Pill Wins Approval*, WALL ST. J. (last updated May 28, 2021), https://www.wsj.com/articles/amgen-wins-approval-for-pathbreaking-lung-cancer-drug-11622220249.

[125] *Id.* at A6.

combination or sequentially with other medicines. LUMAKRAS™, however, faces imminent competition from Mirati Therapeutics, Inc., Eli Lilly & Co., and Revolution Medicines, Inc., each of which is advancing toward clinical trials with similar drugs.[126] The bottom line is none of these patented pharmaceuticals is guaranteed to provide private investors with any financial return. As an industry analyst observed: "[T]he jury's still out."[127] And that is after forty years of largely private funding in this one area of cancer research.[128]

To state the obvious, investing in the research, development, and obtaining FDA approval to bring a pharmaceutical drug to market entails a great deal of risk, often over decades. Therefore, if the return on such investment is not commensurate with these economic realities, there are other options for a rational investor to obtain a modest profit with little risk. The inevitable result will be a dearth of funds needed to develop drugs to cure disease, particularly those that affect only a small segment of the population. The Yale Article does not begin to discuss the consequences to the health of American citizens if private capital begins to move out of the pharmaceutical space.

Finally, the Yale Article does not consider that the Court of Federal Claims rarely adjudicates Section 1498(a) cases. The court's website reflects that from June 20, 2003 to March 1, 2022, approximately ninety cases invoking Section 1498(a) were filed; almost all, however, were dismissed or settled.[129] Another relevant fact not considered by the Yale Article is that in the last thirty-eight years, the Federal Circuit has considered only four cases where awarded Section 1498(a) damages were subject to an appeal; all were affirmed.[130] Three other Section 1498(a) cases were settled

---

[126] *Id.*

[127] *Id.*

[128] *Id.*; *see also* J.P. Carroll, *How Long Does it Take to Get a Drug Approved?* BIOTECHNOLOGY INNOVATION ORG.: BIOTECHNOW (Feb. 16, 2021), https://www.bio.org/blogs/how-long-does-it-take-get-drug-approved ("From 2011–2020, a drug in a Phase I clinical trial had a 7.9% likelihood of approval."); DiMasi et al., *supra* note 40, at 23 (reporting only approximately 12% of investigational medicines that reach clinical trials receive approval from FDA).

[129] *See U.S. Court of Federal Claims Opinion Search*, U.S. CT. OF FED. CLAIMS, https://www.uscfc.uscourts.gov/opinion-search (June 20, 2003 is the earliest date on the website of the United States Court of Federal Claims issuing a Section 1498(a) opinion.).

[130] *See* FastShip, LLC v. United States, 892 F.3d 1298, 1310 (Fed. Cir. 2018) (affirming a $7,117,271.82 award, calculated on a base of "the cost of the elements of LCS-1 covered by the [Patents-in-Suit] as of the date of the license" at a 3% royalty rate plus interest); Paymaster Techs., Inc. v. United States, 180 F. App'x 942, 945 (Fed. Cir. 2006) (affirming $55,923,969.47 award, calculated on a base of "postal money orders," determined, but not reported by the parties, at 3.5% royalty rate); Gargoyles, Inc. v. United States, 113 F.3d 1572, 1574 (Fed. Cir. 1997) (affirming damage award (amount not reported) calculated on a base representing the bulk of B/LPS units acquired by the Army at a 10% royalty and a 50% royalty on a small portion of the of the contract representing the development phase); Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998) (on remand affirming Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1569, 1574 (Fed. Cir. 1996) (affirming an award of $3.577 billion calculated on a royalty base of "total spacecraft cost," i.e., the total procurement cost, including payload costs, to the government for eighty-one spacecraft at a 1% royalty rate determined by comparing three other Hughes license offers)).

reporting damage awards,[131] although there may be a few others.[132] The Yale Article also fails to take into account that government infringement would be ongoing and require pharmaceutical patent owners to file new cases every six years to satisfy the statute of limitations.[133] Consequently, the complexity of determining "reasonable compensation" in these cases will consume a large part of the resources of the Court of Federal Claims and transform it into a de facto price control agency. Finally, the Yale Article breezes over the fact that Section 1498(a) damage awards are paid from monies appropriated by Congress to the Judgment Fund.[134] Therefore, it is the American taxpayer who will foot the bill for the government's infringement of pharmaceutical patents.

## V. LEGISLATIVE PROPOSALS TO "BREAK" PHARMACEUTICAL PATENTS OR COMPEL COMPULSORY LICENSING AT ROYALTY RATES SET BY THE GOVERNMENT WILL FACE SIGNIFICANT LEGAL CHALLENGES

The Prescription Drug Price Relief Act of 2019, Senate Bill 102, which Senator Sanders introduced, if enacted, would authorize the HHS Secretary to infringe pharmaceutical patents or require the owners thereof to enter compulsory licenses at royalty rates established by HHS.[135] Other pending legislation proposals include similar remedial measures directed to address the COVID emergency.[136]

The purpose of Senate Bill 102, as set forth in the title of Section 3, is: "Ending Government-Granted Monopolies for Excessively Priced Drugs."[137] The premise of this proposed legislation is incorrect as a matter of law. As the first Chief Judge of the Federal Circuit pronounced:

> **A patent, under [35 U.S.C. § 262] is property. Nowhere in any statute is a patent described as a monopoly**. The patent right is but the right to

---

[131] Honeywell Int'l, Inc. v. United States, 114 Fed. Cl. 637, 639 (Fed. Cl. 2014) (Stipulated Final Judgment awarding plaintiff $75 million); *see also* Jenna Greene, *Judgment Fund: Feds Paid $87M in Patent Cases*, NAT'L L. J. (Apr. 6, 2015). Two other Section 1498(a) cases also were settled. Advanced Aerospace Techs., Inc. v. United States, 132 Fed. Cl. 696 (Fed. Cl. 2017) (final judgment order awarding plaintiff $12.5 million after trial, but before a final decision was issued) and CANVS Corp. v. United States, No. 10-540 C, 2016 U.S. Claims LEXIS 1248 (Fed. Cl. Sept. 7, 2016) (final judgment order awarding plaintiff $14 million after claim construction).

[132] *See, e.g.*, Boeing Co. v. United States, 86 Fed. Cl. 303, 321–22 (Fed. Cl. 2009) (determining the royalty base corresponded to the value of external tanks sold to the National Aeronautics and Space Administration to which a 1.25% royalty was applied to derive "income flows" of "approximately $16.9 million"); *see also* Securitypoint Holdings, Inc. v. United States, 156 Fed. Cl. 750, 793 (Aug. 31, 2021) (establishing an interim royalty of $103,685,510).

[133] *See* 28 U.S.C. § 2501.

[134] *See* 31 U.S.C. § 1304; *see also* Brennan et al., *supra* note 2, at 347 n.336.

[135] *See* Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019).

[136] *See* Pandemic Emergency Manufacturing Act of 2021, S.187, 117th Cong. (2021) (establishing an Emergency Office within HHS to manufacture and distribute medical products to address COVID-19 or medical products that are in short supply or vulnerable to shortage); *see also* Pandemic Emergency Manufacturing Act of 2021, H.R. 728, 117th Cong. (2021) (same).

[137] S. 102.

> exclude others, the very definition of 'property.' . . . Patents are valid or invalid under the statute, 35 U.S.C. It is but an obfuscation to refer to a patent as 'the patent monopoly[.]'[138]

Other federal appellate courts also have recognized that "[t]he loose application of the pejorative term 'monopoly,' to the property right of exclusion represented by a patent, can be misleading. Unchecked it can also destroy the constitutional and statutory scheme reflected in the patent system."[139] This reflects the primacy of patent law, which "antedate[s] the Sherman Act by a century, [and is] not an 'exception' to the antitrust laws [because] patent rights are not legal monopolies in the antirust sense of that word."[140] A patent grants "the right to exclude others from profiting by [a] patented invention."[141] Therefore, patent law is viewed as an "exception to antitrust law, and the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability."[142]

It is unfortunate that public discourse often overlooks that the right to exclude others from making, using, or selling a patented product affords the patent owner only a limited period to sell or license its work, nothing more.[143] Indeed "[t]he sphere that a patent holder can occupy is circumscribed by prior art, shared with those who have overlapping patent rights, frustrated by limitations of the market, and ultimately, truncated by the passage of time. These limitations are essential elements of the patent grant that keep its power in check."[144]

For these reasons, the Supreme Court has recognized that "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion[.]"[145] If a patent does not convey market power, *ipso facto* it does not convey monopoly power. Since the premise of Senate Bill 102[146] is that patents

---

[138] Schenck v. Nortron Corp., 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (emphasis added).

[139] Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1160 n.8 (6th Cir. 1978).

[140] Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367 (Fed. Cir. 1984); *see also* Ames v. Howard, 1 F. Cas. 755, 756 (C.C. D. Mass. 1833) (stating that patents are "not to be treated as mere monopolies odious in the eyes of the law, and therefore not to be favored").

[141] Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).

[142] FTC v. Actavis, Inc., 570 U.S. 136, 161 (2013) (Roberts, C.J., dissenting).

[143] Robin Feldman, *Patent and Antitrust Different Shades of Meaning*, 13 VA. J.L. & TECH. 5, 4, 11 (2008).

[144] *Id.* at 12.

[145] Ill. Tool Works, Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45–46 (2006); *see also* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 4 (Apr. 6, 1995) (footnote omitted), https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf (announcing that neither enforcement agency will presume that "a patent . . . necessarily confers market power upon its owner. Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes . . . to prevent the exercise of market power. If [an intellectual property right] does confer market power, that market power does not by itself offend the antitrust laws. As with any other . . . asset that enables its owner to obtain significant supracompetitive profits, market power (or even a monopoly) that is solely 'a consequence of a superior product, business acumen, or historic accident' does not violate the antitrust laws. Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others.").

[146] Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019).

are monopolies, the bill is contrary to antitrust law, and actions by HHS to implement Senate Bill 102 likely would face a direct challenge under the APA.[147]

For example, Section 2(b)(1)(A) of Senate Bill 102 mandates: "The Secretary shall determine that any name brand drug for which the domestic average manufacturing price exceeds the median price[148] charged for such drug in the 5 reference countries to have an excessive price."[149] Once a drug is deemed to be excessively priced, under Section 3(a)(1) and (2), the Secretary "shall waive or void any government-granted exclusivities with respect to such drug [granted under the Hatch–Waxman Act] . . . and shall grant open, non-exclusive licenses allowing any person to make, use, offer to sell or sell, or import into the United States such drug[.]"[150]

Without specifying how a "median price"[151] would be determined,[152] or simply leaving the decision whether a drug's price is "excessively priced" to the unfettered discretion of HHS, would be considered by the federal courts as classic examples of "arbitrary" agency action.[153]

Section 3 of Senate Bill 102 also provides that if a brand name drug price is excessive, the HHS Secretary shall 1) waive or void any exclusive rights granted to the drug's manufacturer by the government to make or sell the drug; and 2) regardless of any applicable patents, grant open, non-exclusive licenses so that any person, organization, or company may make, import, or sell the drug in the United States.[154]

Thus, Senate Bill 102 authorizes the HHS Secretary to "void" or "waive" pharmaceutical patents in direct conflict with the only two laws by which a patent may be declared invalid. First, 28 U.S.C. § 1338(a) specifies: "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." Second, the America Invents Act, provides for inter partes Review[155] and post-grant review[156] of patent validity before the Patent Trial and Appeal Board, subject to review by the Federal Circuit.[157] Authorizing an executive department with no responsibility for the issuance of a patent to invalidate one, without judicial review,

---

147 *See* 5 U.S.C. § 706(2)(A).

148 *See* S. 102.

149 *Id.*

150 *Id.*

151 A "median price" is a price in the middle *i.e.,* "an ordered set of [prices] below and above which there is an equal number of [prices]." *Median*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/median (last visited Sept. 12, 2022).

152 Since the price of the like-kind drugs selected by the HHS Secretary for the data set will determine the "median," using this methodology is subjective and the results can be skewed. For example, if four like-kind drug prices are used to determine the median, e.g., $4.50, $5.75, $6.00, and $6.25, the median would be $5.87. If the price of only two like-kind drugs is used to determine the median, e.g., $5.00 and $7.00, the median would be $6.00.

153 *See* 5 U.S.C. § 706 (2)(A).

154 *See* S. 102.

155 *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

156 *Id.* at § 321, 125 Stat. 306.

157 Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373–74 (2018) (holding that the procedural similarities used by federal trial courts and the USPTO Patent Trial and Appeal Board during inter partes review did not violate Article III because the substantive decisions of both are subject to review by the United States Court of Appeals for the Federal Circuit).

would be an unprecedented and serious encroachment on the jurisdiction of Article III judges.[158]

Finally, Section 3 of Senate Bill 102 authorizes the HHS Secretary to grant "open, non-exclusive licenses" allowing others to manufacture, import, or sell patented drugs within the United States.[159] Again, nothing in the history of Section 1498(a) or case law supports such an arbitrary exercise of executive authority, nor should federal courts countenance it.

## VI. CONCLUSION

As a prominent Research Professor and Director in one of the nation's most prestigious healthcare and business institutions testified at a recent congressional hearing:

> [I]t is tempting to cave to the crass political calculus that purports to increase access [to pharmaceutical drugs] in a visible way today and obscures the potential long-term costs[, but] . . . once we observe the magnitude of those costs most elected officials making these decisions will have moved on to other careers. But the goal of policy is to carefully weigh those future costs and not believe snake oil promises that strict and large price regulations can cure all of our ills with no side effects.[160]

Although initial prices of some patented pharmaceutical drugs in the past have been higher in the United States than in countries with price controls and less rigorous regulatory requirements,[161] it would be an extremely dangerous undertaking for the government to upend a patent system that has enabled millions of lives to be saved

---

[158] *See id.* at 1380–86 (2018) (Gorsuch, J., dissenting) ("'It has been settled by repeated decisions of this court that when a patent has [been issued by] the Patent Office, it . . . is not subject to be revoked or cancelled by the President, or any other officer of the Government. It has become the property of the patentee, and as such is entitled to the same legal protection as other property.'" (quoting McCormick Harvesting Machine Co. v. Aultman, 169 U.S. 606, 608–09 (1898)); *see also* Minerva Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298, 2318 (2021) (Barrett, J., dissenting) ("'[A patent] was manifestly intended by Congress to surround the conveyance of patent property with safeguards resembling those usually attaching to that of land.'" (quoting Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co., 266 U.S. 342, 349 (1924)); Adam Mossoff, *The Constitutional Protection of Intellectual Property*, THE HERITAGE FOUND. (Mar. 8, 2021) (reviewing "Founding Era" and 19th Century court decisions and other source material documenting that patents historically have been treated the same in law as private property).

[159] *See* S. 102.

[160] Statement of Garthwaite, *supra* note 40, at 7.

[161] PHRMA, MODERNIZING DRUG DISCOVERY, DEVELOPMENT, AND APPROVAL 1 (Mar. 31, 2016), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/proactive-policy-drug-discovery.pdf ("Developing an innovative medicine is a lengthy and complex process, taking an average of 10 or more years. The clinical trial component alone takes roughly six to seven years. With just 12 percent of drugs that enter clinical trials resulting in an approved medicine, the average research and development cost for each successful drug is estimated at $2.6 billion (including the cost of failures). Against this backdrop . . . reforms at the [FDA] would enhance the competitive market for biopharmaceuticals, drive efficiency in drug development and discovery and help hold down costs."); *see also A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Markets*, *Hearing Before the S. Comm. on the Judiciary, Subcomm. on Competition Policy, Antitrust, and Consumer Rights*, 117th Cong. (2021) (statement of Alden F. Abbott, Senior Research Fellow, Mercatus Center, George Mason University) ("Without significant regulatory reform, significant distortions of competition will remain in pharmaceutical markets.").

and has made substantial contributions to the growth of the American economy over the last century.

Section 1498(a) is not a Rx to reduce drug prices![162]

[162] Some policymakers in the current Administration agree. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY 10 (Sept. 9, 2021) (Neither HHS infringement of pharmaceutical patents nor mandating compulsory licenses set at a royalty rate determined by HHS is recommended to reduce drug prices.).